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December 13, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room # 1061
Rockville, MD 20852

RE: Docket number2005D-0330, Draft Guidance for Industry and FDA Review Staff on Collection of Platelets by Automated Methods.

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To Whom It May Concern:

For the past few years, the United States has been facing a national blood shortage. Blood banks, legislators and even the president have promoted voluntary blood donations. Despite these initiatives, hospitals across the country are forced to delay surgeries and patient safety is placed in jeopardy. Automated blood collections have a significant role to play in alleviating our national blood shortage.

Although the above referenced document contains a number of long overdue changes to current guidances on automated blood collection, the document ignores decades of experience in collecting platelets by automated methods and ignores nearly half a century of plasma collections by automated methods. The extensive real-world experience in plasma and platelet collections, eloquently speaks to the issue of the safety of these procedures. This document ignores this wealth of knowledge and seeks to roll back collection guidelines to those appropriate in the era of the Korean War.

At a time that experience clearly demonstrates the safety of automated blood collections, the United States Food and Drug Administration should be promoting increased blood donations within the demonstrated safety profile of these donations. Instead, the Agency appears to be exacerbating the current blood shortage by rolling regulations back to the dark ages of automated blood collection. At the same time the Agency is pushing a vital component of our country's healthcare system toward disaster.

I am attaching specific comments related to this draft guidance for your review.

Sincerely,

David Witthaus
Director of Operations, Hematology / Reference Laboratory

2005D-0330

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BloodSource
Sacramento, CA

Comments
Guidance for Industry and FDA Review Staff
Collection of Platelets by Automated Methods
Draft Guidance
September 2005

Page	Guidance	Comment
4	Section II B. Definitions	The guidance does not differentiate between a primary and a concurrent component (e.g., During a RBC / plasma procedure is the RBC or the plasma a concurrent component).
5	Section III B. Donor Management	The guidance makes it clear that a pre-donation platelet count is optional "If you cannot test the donor before the first donation …, you should evaluate the donor's WBC and platelet counts after the first collection". Despite the position that the pre-test is optional, position the guidance in two other instances on page 5 indicated that pre-testing should be performed, "You should perform a pre-donation platelet count"; "Prior to the first donation, test Platelets, Pheresis donors for…" The guidance gives sparse direction regarding when the pre-testing is required and when it is merely desirable.
5	Section III B. Donor Management	The wording in the guidance should be expanded to provide for the use of an average of prior platelet counts to set collection parameters. This averaging is a common and time-proven practice to estimate a donor's platelet count.

Page	Guidance	Comment
6	Section III B. Donor Management	Using modern apheresis technology, the safety and yield of collection procedures has continued to improve. Some donors can give as many as three platelet components in a single donation. By counting each component as a donation toward the 24 donations in a year these donors could donate only eight times per year Millions of apheresis donations have taken place with the 24 donations per year rule in effect. This experience speaks volumes about the safety of this procedure. The safeguards for the donor exist in regulation limiting volume loss per procedure and in the algorithms build into apheresis equipment (licensed by the FDA) that limit the number of platelet products that can be collected based on platelet count and blood volume. Nearly a half century of experience proves that apheresis collections are safe. Platelet donations should be allowed in acceptance with plasma donations. (12 liter annual loss unless a frequent donor, then 62.4 liters.)
6	Section III B. Donor Management	Current research and a vast body of experience do not support a change in donation frequency. Not only does this proposed regulation ignore donor to donor differences, but it ignores the fact that two platelet donations per week has been proven to be safe by the millions of apheresis donations have taken place under this rule.

Page	Guidance	Comment
8	Section V B. Target Platelet Yield	Although directing the programming of apheresis equipment at these levels may seem appropriate for this guidance it is not appropriate for three reasons: • This guidance would put the FDA in the business of specifying operational details of collections. The FDA should specify the requirements of products. • This guidance ignores the fact that different apheresis instruments collect with different levels of accuracy relative to targeted yields. Additionally, some blood centers perform pre-donation platelet counts on all donors contributing to very accurate platelet yields. Contrast these collections to collections performed on donors that do not have platelet counts available for setting collection parameters. • Future apheresis instruments are likely to become more accurate in their collections, thus rendering this proposed guidance in target yields obsolete. Additionally, it is significant to note that testing performed on double and triple collections after collection will result in products not meeting specifications for these products being converted to an acceptable yield product (single or double), this there is no risk of producing a platelet product without an adequate platelet dose.
11	Section: VI D. Product Performance Qualification	The sampling scheme outlined in the guidance ignores the volume of automated collections performed, thus a blood center that utilizes only a single instrument will have a ten-fold greater collection per machine than a center with ten instruments. Despite this exponentially higher burden, no additional assurance of proper operation is gained. The same standard for validation should be applied to equipment regardless of facility size.

Page	Guidance	Comment
11	Section: VI D. Product Performance Qualification	The requirement to perform 500 collections without a positive bacterial detection result is ill advised for two reasons: • Bacterial detection is not an FDA required test. • Detection of bacteria in a contaminated unit is a good thing. This is true if it is the first unit tested in a validation or if it is the 501st unit tested.
15	Section: VII A. Standard Operating Procedures	Total volume loss (and donation frequency) should be identical to the time-proven limits on plasma donors: 12 liters for infrequent donors; 62.4 liters for frequent donors.
17	Section: VII B.	Post collection cell counts are particularly unreliable as the donor's fluid balance is in flux. The most accurate indicator of the donors post collection platelet adequacy is the pre-collection platelet count and the validated (licensed) collection limits for a given procedure.
19	Section: VII C. Component Testing	QC recommendations are vague and inconsistent. The guidance needs to account for the number of collection procedures performed and how the statistics will be used (per machine, per site, per organization).
19	Section: VII C. Component Testing	Promoting the use of scan statistics will create inconsistent quality metrics as blood centers manipulate assessment windows and number of data points. Ultimately, scan statistics will be confusing for FDA inspectors and is unlikely to improve quality.